USDA-APHIS

Our Role in the Regulation of Products of Biotechnology

National Academy of Sciences

Public Meeting

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Our Regulatory Framework for Protecting Plant Health: Overview

Law: Plant Protection Act

Protection Goal: To protect plants and plant products from plant pests.

Regulation: 7 CFR 340

https://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology

Our Regulatory Framework for Protecting Plant Health: Overview

Organisms are subject to our regulations if:

- The organism has been altered or produced through genetic engineering (recombinant DNA techniques),

and

- The organism is produced using plant pests (i.e. donor, recipient, or vector is a plant pest) *or*
- There is otherwise a reason to believe that the organism is a plant pest.

Our Regulatory Framework for Protecting Plant Health: Overview

BRS regulates a variety of GE organisms including:

- Any organism engineered using plant pests – **plants** comprise the largest share of our work
- Genetically engineered plant pests – this encompasses bacteria, fungi, viruses, and invertebrate animals such as **insects**, arachnids, and nematodes.

Regulation of GE Organisms at APHIS BRS

- Not all GE plants are regulated by APHIS – there must be a plant pest component.
- List of organisms we consider to be plant pests is in the regulations at 7 CFR 340.2
- We have a formal process by which a developer can inquire and receive and answer as to whether a given GE plant is within the scope of regulations at 7 CFR 340.

Regulated Activities

- If a GE organism is regulated, a Permit or Notification is required for the following activities:

  - Importation
  - Interstate movement
  - Field test (confined release)

Confined Field Trials

- Field testing focuses primarily on confinement; a full data package on the GE trait is not needed.
- Risk assessment relies on familiarity with the plant, the trait, and the environment.
- Characteristics of the plant are often key:
  - Is it outcrossing of self-pollinating?
  - Is it weedy or invasive?
  - Are there wild relatives?
  - Can the plant or offspring persist after the test is over?
  - Would the trait be expected to change the plants weediness, invasiveness, or reproductive biology?

Petition Process for nonregulated Status

- After safety has been established through field testing and other research activities, a developer may petition APHIS to grant "nonregulated status"
  - No longer a regulated article
  - Free to be moved and planted without permits or further APHIS oversight.

Petition Process for nonregulated Status

- Petition Evaluation
  - Comprehensive scientific review – Team of scientists
  - Crop biology and taxonomy
  - Any genotypic differences
  - Any phenotypic differences
  - Field test reports for all releases conducted in the U.S.
  - Relevant experimental data, publications and other data upon which to base a determination

Petition Process for nonregulated Status

APHIS BRS conducts two evaluations:

- Plant Pest Risk Assessment to determine if the GE organism poses a risk as a plant pest (Plant Protection Act)
- Environmental Assessment or Environmental Impact Statement to broader evaluate environmental impacts of APHIS-BRS decision (National Environmental Policy Act; NEPA)

Petition Process for nonregulated Status

- **Components of a Plant Pest Risk Assessment:**
  - Create pest or disease problems for agriculture.
  - Become a weed.
  - Increase the weediness of sexually compatible plants.
  - Harm non-target organisms (beneficial, endangered).
  - Affect agricultural practices in a way which could create disease and pest problems.
  - Transmit the genes to organisms with which it does not normally interbreed.

GE plants with Nonregulated Status

- APHIS-BRS has made determinations of nonregulated status in response to 120 petitions, representing 17 plant species
- The determination of nonregulated status extends to the GE plant and its offspring
- Actual commercialization of GE plants with nonregulated status is determined by market demand, not the APHIS decision.

GE Plants with [1]Nonregulated Status under 7 CFR part 340

Alfalfa – HT, PQ
Canola – HT, AP, PQ
Corn – HT, IR, AP, PQ
Cotton – HT, IR
Papaya – VR
Soybean – HT, IR, AP, PQ
Sugar Beet – HT
Rose – PQ
Squash – VR
Tobacco – PQ

Apple – PQ
Chicory – AP
Flax – HT
Plum – VR
Potato – IR, VR, PQ, FR
Rice – HT
Tomato – PQ

[1]Nonregulated status does not necessarily mean that the plant is in commercial production

HT – Herbicide Tolerant
IR – Insect Resistant
VR – Virus Resistant
AP – Agronomic Properties
PQ – Product Quality
FR – Fungal Resistant

"Am I Regulated" Letters of Inquiry

- APHIS regulatory scope is limited is strictly defined in the regulations.
- GE organisms lying outside the scope do not require permits or notification and the petition process does not apply.
- APHIS established a formal process of inquiry in 2010 and has since responded to inquiries on 38 organisms with respect to their regulated status.

"Am I Regulated" Letters of Inquiry

- These letters of inquiry and the APHIS response are available on our website.
- The process is case-by-case.
- The process is different than that for determinations of non-regulated status in response to petitions.
- It does not rely on a plant pest risk assessment, but rather on an analysis of whether the organisms meets the definition of a "regulated article" in the regulations.

APHIS Animal Health Authority

Law: Animal Health Protection Act (AHPA)
Virus-Serum-Toxin Act

Regulations: Title 9 CFR
Part 93 – import of animals
Part 71 – interstate movement of animals infected with certain diseases
Part 122 – insects which are vectors of animal diseases
Parts 101-118 – veterinary biologics

APHIS Regulation of GE Insects

- GE insects regulated similar to non-GE insects, on their ability to contain any contagious, infectious or communicable disease of livestock or poultry.
- For the importation or interstate movement of any GE insect, a permit application must be submitted for evaluation to determine the animal health risk of the vector to livestock and poultry.
- APHIS will collaborate with other agencies such as FDA, EPA and CDC to ensure the appropriate regulatory authority and oversight for GE insects.

APHIS Regulation of GE Animals

- FDA takes the lead, and we collaborate when we have overlapping authority
- Regulations limited to animals considered livestock (horses, cattle, bison, sheep, goats, swine, cervids, poultry and other farm-raised animals)
- APHIS applies same standard of review for GE animals as non-GE animals – animal health risk

APHIS Regulation of Veterinary Biologics

- Ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective
- GE organisms regulated as component of final product